

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Greg Swords)	
)	Art Unit: 3774
Serial No. 10/517,843)	
)	
Filed: July 12, 2005)	Examiner: Suba Ganesan
)	
For: Craniofacial Implant)	Attorney Docket No.: 37370/339252

DECLARATION

1. My name is AaronFay, MD. I am over the age of 21, and I am competent to make this declaration based upon my personal knowledge.
2. I am a surgeon who uses the TITAN™ implant, which I understand is the product made according to the above-referenced application.
3. The TITAN™ implant is a porous polyethylene matrix having a metal mesh embedded therein. In some versions of the implant, there is a barrier coating on one or both sides. The TITAN™ implant provides clear and distinct benefits over other craniofacial implants previously on the market.
4. First, porous polyethylene implants for orbital reconstruction *without* a surgical grade metal mesh do not always meet my needs because they do not provide adequate strength needed for certain surgeries, they are not always malleable, they have less shape memory than metal mesh alone, and they are not readily visualized on postoperative radiographs or CT scans. Second, metal mesh alone (not contained within a sheet of thermoplastic resin)

does not always meet my needs because it does not allow for cellular ingrowth, it does not provide a smooth solid barrier surface, which is sometimes needed to completely prevent passage of fluids and other biological matter, and it can be difficult to insert through small incisions because of its sharp or irregular edges.

5. When the TITAN™ implant was introduced, it was the first product on the market to combine porous polyethylene and titanium mesh into one implant by embedding the mesh within polyethylene, obtaining the benefits of both materials.

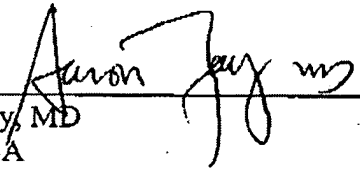
6. Upon its introduction, I was (and I continue to be) quite pleased with the features that the TITAN™ implant provides. It combines strength and flexibility, so that I can bend the implant and it maintains its shape. It also provides different options – implants that allow fibrovascular ingrowth on both sides (porous/porous), fibrovascular ingrowth on only one side (porous/barrier), or preventing ingrowth completely (barrier/barrier). I currently use the TITAN™ implant in many of my large or complex orbital reconstruction surgeries.

7. My decision to use (and continue to use) the TITAN™ implant is not influenced by cost, advertising, my relationship with Porex, nor any other economic or commercial factors. I choose to use TITAN™ implants because the features they provide are highly superior to any other product on the market. The combination of porous polyethylene with a surgical grade metal mesh embedded therein is why I (and many of my colleagues) continue to purchase and use the TITAN™ implant.

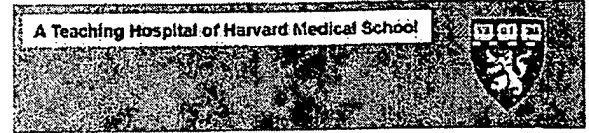
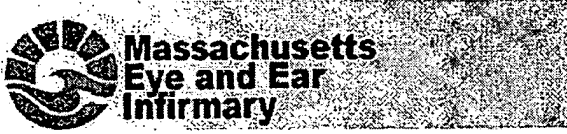
8. As the person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under
§ 1001 of Title 18 of the United States Code.

Dated: 3 September 2008



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Aaron Fay, MD

Assistant Clinical Professor of Ophthalmology , Harvard Medical School

Department of Ophthalmology,
Interim Director, Ophthalmic Plastic Surgery

Specialty Area

Ophthalmic plastic surgery; vascular anomalies

Address

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Clinical Background

Foreign Languages: Spanish

Medical School

Columbia University College of Physicians and Surgeons, 1993

Residency

Edward S. Harkness Eye Institute, New York, NY, *Ophthalmology*

Fellowships

Ophthalmic Pathology, 1997-98, MGH, Frederick A. Jakobiec, MD

Ophthalmic Plastic And Reconstructive Surgery, 1997-99, MEEI, Peter A.D. Rubin, MD

Board Certification

Ophthalmology, 1999

Clinical Interests

Clinical Interests: Periocular vascular tumors, tear duct surgery, eye socket tumors, eyelid reconstruction. Current Research: Laser treatment of tear ducts; Blood vessel and lymphatic vessel tumors; Development of the infantile eye socket

Publications

A complete list of research publications can be seen at www.pubmed.gov. Type the physician's name at the top, where it says 'for' and the physician's research publications will appear.